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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,701	11/25/2003	David Hung	12.009011-2	6286

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,701	HUNG ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 1-34 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 27-60 have been renumbered according to Rule 1.126. A complete response to this action will include a properly numbered claim set.

Claims 1-34 are pending and examined on the merits.

Priority

Acknowledgement is made of applicants claim to an earlier effective filing date via 09/313,463, filed May 17, 199 and provisional application 60/117,281. Upon review of each application it is noted that there is o description of a device which is a microchip as an alternative to an osmotic pump. Accordingly, benefit will be extended only to 09/502,206, filed February 10, 2000 for claims 1-34 which include a microchip as an embodiment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7, 9-17, 19, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al (U.S. 4,838,862) in view of Sukumar (U.S. 5,763,415) and Bolivar et al (Acta Radiologica, March 1997, Vol. 38, pp. 240-242).

Claim 1 is drawn to a device for delivering an agent to a breast milk duct over time, said device comprising; a unit for holding the agent to be delivered to the breast duct, said unit being sized and configured to be positioned and supported on a nipple, and an elongated member for delivering the agent from the unit to the breast duct, said elongated member being in communication within said unit and being sized for positioning within the breast duct.

Claim 2 embodies the device to claim 1 wherein said unit comprises a reservoir for holding the agent to be delivered to the elongated member

Claim 3 embodies the device to claim 2 wherein said reservoir is sized to hold a volume of the agent in the range of from about 0.001 ml to 10 ml.

Claim 4 embodies the device to claim 2 wherein said unit comprises a pump for delivering the agent from the reservoir to the elongated member when the elongated member is positioned within the breast duct.

Claim 5 embodies the device of claim 4 wherein said pump is osmotic.

Claim 7 embodies the device of claim 1 wherein said unit comprises an osmotic pump for delivering the agent to the elongated member when the elongated member is positioned within the breast duct.

Claim 9 embodies the device of claim 1 wherein said elongated member extends substantially perpendicular to a nipple engaging surface of the unit.

Claim 10 embodies the device of claim 1 wherein said elongated member includes a portion for securely maintaining the elongated member within the breast duct.

Claim 11 embodies the device of claim 10 wherein said portion of the elongated member includes a protruding member for engaging a wall of the breast duct.

Claim 12 is drawn to a device for delivering an agent to a breast milk duct, said device comprising: a unit for holding the agent to be delivered to the breast duct, said unit being sized

and configured for residing on a nipple surface, and an elongated member for delivering the agent from the unit to the breast duct, said elongated member being in communication with said unit, sized for positioning within the breast duct and having a retaining member for holding the elongated member in the breast duct.

Claim 13 embodies the device of claim 12 wherein said device includes an outer boundary that is shaped and configured for being fully supported on a nipple.

Claim 14 embodies the device to claim 12 wherein said unit comprises a reservoir for holding the agent to be delivered to the elongated member

Claim 15 embodies the device according to claim 14 wherein said reservoir is sized to hold a volume of the agent in the range of from about 0.001 ml to 10 ml.

Claim 16 embodies the device to claim 15 wherein said unit comprises a pump for delivering the agent from the reservoir to the elongated member when the elongated member is positioned within the breast duct.

Claim 17 embodies the device of claim 15 wherein said pump is osmotic.

Claim 19 embodies the device of claim 12 wherein said unit comprises an osmotic pump for delivering the agent to the elongated member when the elongated member is positioned within the breast duct.

Claim 21 embodies the device of claim 12 wherein said elongated member extends substantially perpendicular to a nipple engaging surface of the unit.

Claim 22 embodies the device of claim 12 wherein said remaining member includes a protrusion for engaging a wall of the breast duct.

Baker et al teach a small portable osmotic pump which is 1.3 cm thick, 3.5 cm in diameter with a delivery rate of 1 ml per day for 24 hours (column 7, Example 1) which fulfills the specific embodiment of claims 3. Baker et al teach that the pump is held in place outside of the body and may be used in conjunction with a subcutaneous drug delivery set (column 4, lines 49-51 and lines 62-64). Baker et al do not teach the specific configuration required for support on a nipple, nor an elongated member for delivering agent into a breast duct.

Sukumar teaches the localized treatment of a mammary gland comprising contacting the ductal epithelium with an anti-cancer agent via ductal cannulation (column 7, lines 46-60).

Bolivar et al teach the use of a Kopans guide for an anchor within the mammary ducts. Bolivar et al teach that intraductal growths are most commonly near the areolar region requiring the insertion of the anchor only 1-2 cm within the breast (page 241).

It would have been prima facie obvious at the time the claimed invention was made to configure the small osmotic pump of Baker to be supported on a nipple, and to use a cannula to protrude from the breast and the Kopans guide to position the cannula at an intraductal lesion. One of skill n the art would have been motivated to do so by the teachings of Sukumar et al on the intraductal administration of chemotherapeutic agents and the teachings of Bolivar on the relative accessibility of intraductal lesions and the anchoring of a guide with in the breast. One of skill in the art would have been motivated to keep the cannula correctly placed during the treatment.

Claims 23-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes et al (U.S. 3,845,770) in view of Sukumar (U.S. 5,763,415) and Bolivar et al (Acta Radiologica, March 1997, Vol. 38, pp. 240-242).

Claim 23 is drawn to a device for delivering an agent to a breast milk duct over time, said device comprising: an indwelling unit for holding the agent to be delivered to the breast duct, said indwelling unit being sized and configured for being positioned and maintained within a portion of a breast duct, and an elongated member extending from said unit, wherein said elongated member can be positioned to extend out of said breast duct when said indwelling unit is positioned within the breast duct. Claim 24 embodies the device of claim 23 wherein said elongated member includes a tether that provides retrieval of the indwelling unit from within the breast duct. Claim 25 embodies the device of claim 23 wherein said unit includes a reservoir and said elongated member includes a lumen for delivering fluid to said reservoir when said reservoir is positioned within the breast duct. Claim 26 embodies the device of claim 23 wherein said elongated member includes an internal lumen for delivering a fluid to the indwelling unit. Claim 27 embodies the device according to claim 23 wherein said indwelling unit comprises a reservoir

for holding the agent to be delivered to the breast duct. Claim 28 embodies the device of claim 27 wherein said reservoir is sized to hold a volume of the agent in the range of from about 0.001 ml to 10 ml.

Theeuwes et al teach an implantable drug delivery device shaped like a bullet (column 9, lines 15-17), wherein said device is an osmotic pump for providing neoplastic agents (column 11, line 27). Theeuwes et al teach that the device will provide 0.01 cc to 5 cc of fluid per hour, day or longer (column 12, lines 53-57 and column 16, lines 23-30).

Sukumar teaches the localized treatment of a mammary gland comprising contacting the ductal epithelium with an anti-cancer agent via ductal cannulation (column 7, lines 46-60).

Bolivar et al teach the use of a Kopans guide for an anchor within the mammary ducts. Bolivar et al teach that intraductal growths are most commonly near the areolar region requiring the insertion of the anchor only 1-2 cm within the breast (page 241).

It would have been prima facie obvious at the time the claimed invention was made to configure a bullet shaped indwelling osmotic pump for positioning within a breast duct, said implantable pump having a tether which extends out of the breast duct for removal. One of skill in the art would have been motivated to do so by the teachings of Sukumar et al on the localized delivery of antineoplastic drugs to breast epithelium and the teachings of Bolivar et al about the Kopans guide for positioning a wire within a breast duct. One of skill in the art would be motivated to position the implantable pump at the correct location via the Kopans guide so as to provide the most efficacy in the local treatments and to have a pump which would be removed when depleted and replaced by a filled device.

Claims 1-3, 6, 8-15, 18, 20-28, 31, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santini et al (U.S. 5,797,898) in view of Sukumar (U.S. 5,763,415) and Bolivar et al (Acta Radiologica, March 1997, Vol. 38, pp. 240-242).Claim 6 embodies the device of claim 1 wherein said unit is capable of delivering a volume of the agent in a range from about 0.0001 ml per day to about 0.001 ml per hour. Claim 8 embodies the device of claim 1 wherein said unit comprises a microchip for delivering the agent to the elongated member when the elongated member is positioned within the breast duct. Claim 18 embodies the device of claim 12 wherein said unit is capable of delivering a volume of the agent in a range from about 0.0001

ml per day to about 0.001 ml per hour. Claim 20 embodies the device of claim 12 wherein said unit comprises a microchip for delivering the agent to the elongated member when the elongated member is positioned within the breast duct.

Claim 23 is drawn to a device for delivering an agent to a breast milk duct over time, said device comprising: an indwelling unit for holding the agent to be delivered to the breast duct, said indwelling unit being sized and configured for being positioned and maintained within a portion of a breast duct, and an elongated member extending from said unit, wherein said elongated member can be positioned to extend out of said breast duct when said indwelling unit is positioned within the breast duct. Claim 24 embodies the device of claim 23 wherein said elongated member includes a tether that provides retrieval of the indwelling unit from within the breast duct. Claim 25 embodies the device of claim 23 wherein said unit includes a reservoir and said elongated member includes a lumen for delivering fluid to said reservoir when said reservoir is positioned within the breast duct. Claim 26 embodies the device of claim 23 wherein said elongated member includes an internal lumen for delivering a fluid to the indwelling unit. Claim 27 embodies the device according to claim 23 wherein said indwelling unit comprises a reservoir for holding the agent to be delivered to the breast duct. Claim 28 embodies the device of claim 27 wherein said reservoir is sized to hold a volume of the agent in the range of from about 0.001 ml to 10 ml.Claim 31 embodies the device of claim 23 wherein said indwelling unit is capable of delivering a volume of the agent in a range from about 0.0001 ml per day to about 0.001 ml per hour. Claim 33 embodies the device of claim 23 wherein said indwelling unit comprises a microchip for delivering the agent to the breast duct when the indwelling unit is positioned within the breast duct. Claim 34 is drawn to a device for delivering an agent to a breast milk duct over time, said device comprising: an indwelling unit for holding the agent to be delivered to the breast duct, said unit including a microchip and being sized and configured to be positioned and supported within a breast duct, and an elongated member secured to the indwelling unit, wherein said elongated member extends out of the breast when the indwelling unit is positioned within the breast duct.

Santini et al teach small implantable microchip devices that function as drug dispensing agents (column 3, lines 9-42). Santini et al teach that for in vivo applications the entire device, including the power supply is encapsulated in a biocompatible material (column 6, lines 21-25).

Santini et al teach that the microchips can be implanted into a patient by injection (column 11, lines 20-23). Santini et al teach the delivery of drugs by means of release from a reservoir which can be controlled by a preprogrammed microprocessor or remote control (column 10, lines 27-48).

Sukumar teaches the localized treatment of a mammary gland comprising contacting the ductal epithelium with an anti-cancer agent via ductal cannulation (column 7, lines 46-60).

Bolivar et al teach the use of a Kopans guide for an anchor within the mammary ducts. Bolivar et al teach that intraductal growths are most commonly near the areolar region requiring the insertion of the anchor only 1-2 cm within the breast (page 241).

It would have been prima facie obvious at the time the claimed invention was made to configure a bullet shaped indwelling microchip reservoir for positioning within a breast duct, said microchip having a tether which extends out of the breast duct for removal. One of skill in the art would have been motivated to do so by the teachings of Sukumar et al on the localized delivery of antineoplastic drugs to breast epithelium and the teachings of Bolivar et al about the Kopans guide for positioning a wire within a breast duct. One of skill in the art would be motivated to position the implantable pump at the correct location via the Kopans guide so as to provide the most efficacy in the local treatments and to have a microchip reservoir which would be removed when depleted and replaced by a filled microchip.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A.Canella, Ph.D.
9/5/2006

KAREN A. CANELLA PH.D
PRIMARY EXAMINER